510(K) SUMMARY

MAR 2 8 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

GETEMED Medizin- und Informationstechnik AG
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Date Summary Prepared: March 26, 2013

2. **Name of the Device:** CardioMem® Models CM 4000/CM 4000B

3. **Device Classification:** Class II, 21 CFR Part 870.2800

4. **Common or Usual Name:** Holter Recorder, Product Code MWJ

5. **Predicate Device Information:**

Device	Manufacturer	510(k) Number
CardioMem® CM 3000	GETEMED Medizin- und Informationstechnik AG	K022540 "Rz153+/ CardioID+"
CardioMem® CM 3000-12 BT	GETEMED Medizin- und Informationstechnik AG	K063042

6. **Device Description:**

The CardioMem® Models CM 4000/CM 4000B digital Holter recorders are intended to continuously record ECG data. The CM 4000/CM 4000B perform no cardiac analysis by themselves and are intended to be used with a Holter ECG Analysis Software package. The recorder supports the user throughout all phases of recording Holter ECGs, from applying the electrodes and entering patient demographic data up to inspecting the ECG waveforms. The digital recorders CardioMem® Models CM 4000/CM 4000B devices allow a qualified trained physician or health care professional to record the patient's ECG for the long term. The data is then downloaded to a computer containing a Holter ECG Analysis Software package. This data is then reviewed by a qualified health professional or a physician.

The only difference between the two CM 4000 models CM 4000 and CM 4000B is the battery size. The CM 4000 has a AAA battery compartment whereas the CM 4000B has a AA battery compartment, which results in a different shape of the housing and the weight of the recorder.

7. **Intended Use:**

The CardioMem® Models CM 4000/CM 4000B digital Holter recorders are intended to continuously record EGC data. The CardioMem® Models CM 4000/CM 4000B perform no cardiac analysis by themselves and are intended to be used with an ECG analysis software package. The recorded data are downloaded to a PC for analysis and subsequent evaluation by a trained physician or health care professional.

8. **Comparison to Predicate Devices:**

CardioMem® Models CM 4000/CM 4000B are substantially equivalent to the Holter recorder CardioMem® CM 3000-12 BT (K063042) from GETEMED Medizin- und Informationstechnik AG and the CardioMem® CM 3000 (K022540) from GETEMED Medizin- und Informationstechnik AG. There have been no changes implemented in the modifications to the CardioMem® Models CM 4000/CM 4000B that impact either the fundamental technology or the indications for use. There were only some incremental changes in the devices to improve the usability, the design and to bring the technical details up-to date.

The user interface was improved to a color display with touch functionality. The removable compact flash storage card was replaced by a non-removable SD card. In the CM 3000, the channel for the pacemaker detection had to be chosen at the beginning of the measurement and was fixed for the whole examination. Now the CM 4000/CM 400B automatically choose the best channel for the detection of the pacemaker pulses during the measurement. The data storage for further analysis is now divided into episodes of duration of about one hour instead of one large streaming file. Generally, there was a process of miniaturization for the complete device, so that it is now smaller and lighter.

9. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non-clinical testing that has been conducted include:

a. Electromagnetic compatibility evaluation according to IEC 60601-1-2;
b. Electrical safety test according test to IEC 60601-1

In addition, software validation testing was performed (using a moderate level of software concern) to address the differences between the subject device and predicate device software.

None of the testing demonstrated that the CardioMem® Models CM 4000/CM 4000B brought up any issues of safety or effectiveness.

10. **Discussion of Clinical Tests Performed:**

No clinical testing was performed in order to support safety or effectiveness.

11. **Conclusions:**

CardioMem® Models CM 4000/CM 4000B are very similar to its predicate devices in intended use, design principle, material, or performance to applicable standards. The main modification is the updated user interface to a color display with touch

functionality. Generally, there was a process of miniaturization for the complete device, so that it is now smaller and lighter.

The test results in this submission demonstrated that these small differences do not raise any new questions of safety and effectiveness to the subject device and the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Getemed Medizin – und Informationstechnik AG
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K122272
Trade/Device Name: CardioMem® CM 4000/CM 4000 B
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, ambulatory (without analysis)
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: March 7, 2013
Received: March 8, 2013

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122272

Device Name: CardioMem® Models CM 4000/CM 4000B

Indications For Use:

The CardioMem® Models CM 4000/CM 4000B are Holter recorders which are indicated for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality.

Prescription Use __X___ **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use**_____ **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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